

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Shawn L. Lyons, et al.

Application No.: **Continuation of 10/319,845**

Group Art Unit: Not Yet Assigned

Filed: December 9, 2003

Examiner: Not Yet Assigned

For: METHOD AND APPARATUS FOR
PREPARING MICROPARTICLES USING
IN-LINE SOLVENT EXTRACTION

Information Disclosure Statement

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO/SB/08a/b are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO/SB/08a/b based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior

art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- ☒ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No statement under 37 C.F.R. § 1.97(e) or fee is required.
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
 - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
 - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

- ☐ c. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. It is hereby requested that the Information Disclosure Statement be considered. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(i).
- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.
- ☐ 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☒ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. 10/319,845, filed December 16, 2002 (000166.0098-US02), which is directed to related technical subject matter. The identification of this U.S. Patent

Application is not to be construed as a waiver of secrecy as to this application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

- ☒ 8. Copies of the documents were cited by or submitted to the Office in Application No. 10/319,845, filed December 16, 2002; 09/930,450 (U.S. Patent No. 6,540,393), filed August 16, 2001 and 09/438,656 (U.S. Patent 6,495,166), filed November 12, 1999, which are relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO/SB/08a/b, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 50-0740, referencing Docket No. 000166.00098-US03.

Dated: December 9, 2003

Respectfully submitted,

By 
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Washington, DC 20004-2401
(202) 662-6000

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Shawn L. Lyons
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	000166.0098-US03

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	US-1,626,487	04/1927	Warren	
	AB	US-3,523,906	08/1970	Vrancken et al.	
	AC	US-3,655,166	04/1972	Sauer et al.	
	AD	US-3,691,090	09/1972	Kitajima et al.	
	AE	US-3,737,337	06/1973	Schnoring et al.	
	AF	US-3,773,098	11/1973	Rock, Edward J.	
	AG	US-3,773,919	11/1973	Boswell et al.	
	AH	US-3,891,570	06/1975	Fukushima et al.	
	AI	US-3,960,757	06/1976	Morishita et al.	
	AJ	US-4,050,676	09/1977	Morishita et al.	
	AK	US-4,026,817	05/1977	Ciuti et al.	
	AL	US-4,221,861	09/1980	Naito et al.	
	AM	US-4,334,884	06/1982	Wilke et al.	
	AN	US-4,384,975	05/1983	Fong	
	AO	US-4,389,330	06/1983	Tice et al.	
	AP	US-4,530,840	07/1985	Tice et al.	
	AQ	US-4,940,588	07/1990	Sparks et al.	
	AR	US-5,066,436	11/1991	Komen et al.	
	AS	US-5,076,705	12/1991	Brickhouse et al.	
	AT	US-5,407,609	04/1995	Tice et al.	
	AU	US-5,421,408	06/1995	Stoisits et al.	
	AV	US-5,478,564	12/1995	Wantier et al.	
	AW	US-5,541,172	07/1996	Labric et al.	
	AX	US-5,650,173	07/1997	Alkermes Controlled Therapeutics Inc. II	
	AY	US-5,654,008	08/1997	Medisorb Technologies International, L.P.	
	AZ	US-5,656,299	08/1997	Kino et al.	
	AA1	US-5,670,093	09/1997	Payne, Richard L.	
	AB1	US-5,688,801	11/1997	Janssen Pharmaceutica	
	AC1	US-5,770,231	06/1998	Alkermes Controlled Therapeutics Inc. II	
	AD1	US-5,792,477-A2	08/1998	Rickey et al.	
	AE1	US-5,871,778	02/1999	Kino et al.	
	AF1	US-5,916,598	06/1999	Rickey et al.	
	AG1	US-5,945,126	08/1999	Thanoo et al.	
	AH1	US-5,965,168	10/1999	Alkermes Controlled Therapeutics Inc. II	
	AI1	US-6,110,503	08/2000	Rickey, et al.	
	AJ1	US-6,194,006	02/2001	Lyons, et al.	
	AK1	US-6,291,013-B1	09/2001	Gibson et al.	
	AL1	US-6,395,304	10/2001	Alkermes Controlled Therapeutics Inc. II	
	AM1	US-6,331,317	12/2001	Alkermes Controlled Therapeutics Inc. II	
	AN1	US-6,495,166	12/2002	Alkermes Controlled Therapeutics Inc. II	
	AO1	US-6,540,393	04/2003	Alkermes Controlled Therapeutics Inc. II	

Examiner Signature		Date Considered	
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	Not Yet Assigned
				Filing Date	Concurrently Herewith
				First Named Inventor	Shawn L. Lyons
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket Number	000166.0098-US03

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BA	WO-WO 89/03678	05/1989	Lewis et al.		
	BB	WO-WO 90/13361	11/1990	Tice et al.		
	BC	EP-0486959-A1	05/1992	Canal et al.		
	BD	WO-WO 94/10982	05/1994	Kino et al.		
	BE	WO-WO 95/13799	05/1995	Ramstack et al.		
	BF	WO-WO 97/41837	11/1997	Rickey et al.		
	BG	WO-WO 99/12549	03/1999	Illum et al.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	CA	Baker, J.R., "Motionless Mixers Stir Up New Uses," Chemical Engineering Progress, pp. 32-38 (June 1991).		
	CB	Beck, L.R. et al., Biology of Reproduction, 28:186-195 (February 1983).		
	CC	Bodmeier, R. et al., International Journal of Pharmaceuticals, 43:179-186 (1988).		
	CD	Conti, B. et al., "User of polylactic acid for the preparation of microparticulate drug delivery systems," J. Microencapsulation, 1992, 9(2):153-166, XP 000259942.		
	CE	Jalil, R. et al., Journal of Microencapsulation, 7(3):297-319 (July-September 1990).		
	CF	Koch Engineering Co., Inc., Static Mixing Technology advertisement, pp. 1-15.		
	CG	Li, Wen-I et al., Journal of Controlled Release, 37:199-214 (December 1995).		
	CH	Maa, Y.F. et al., "Liquid-liquid emulsification by static mixers for use in microencapsulation," J. Microencapsulation, 13(4):419-433, XP 000589904 (1996).		
	CI	Maulding, H.V. et al., Journal of Controlled Release, 3:103-117 (March 1986).		
	CJ	Mutsakis, M. et al., "Advances in Static Mixing Technology," Chemical Engineering Progress, pp. 42-48 (July 1986).		
	CK	Sah, Hongkee et al., Pharmaceutical Research, 13:360-367 (March 1996).		
	CL	Sato, Toyomi et al., Pharmaceutical Research, 5:21-30 (1988).		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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